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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,513	07/05/2001	Yi Hu	LEX-0200-USA	9922

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EXAMINER
LI, RUIXIANG

ART UNIT	PAPER NUMBER
1646	12

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,513	HU ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 5-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 5-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed in Paper No. 11 on December 5, 2002 has been entered in full. Claim 5 has been amended. Claims 5-7 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Withdrawn Rejections

The rejection of claim 5 under 35 U.S.C. 112, 2nd paragraph, as set forth at page 6 of the previous Office Action (Paper No. 9, July 30, 2002), has been withdrawn in view of applicants' amendment to the claim.

III. 35 U.S.C. § 101

The rejection of claims 5-7 under 35 U.S.C. 101, as set forth at pages 2-6 of the previous Office Action (Paper No. 9, July 30, 2002), remains.

The applicants' response (Paper No. 11, December 5, 2002; hereinafter "Response") argues that the protein of the present invention belongs to the G-protein coupled receptor (GPCR) family, members of which are well known in the art to be commercially valuable drug targets. Thus, the claimed invention has a well-established utility (page 4, 2nd paragraph). This has been fully considered but is not deemed to be

persuasive because commercial success is not an indication of utility and the commercial value does not simply render the claimed invention a specific, substantial, and credible utility. This is because many products may be commercially successful due to reasons unrelated to the use of the products. For example, a pharmaceutical company may wish to purchase a putative GPCR on the chance that it may turn out to be a drug target in future, even though determining such possibility requires substantial further experimentation. However, such substantial further experiment is not acceptable for patentable utiity. In addition, substantial further experiment may have already been done on some of the GPCRs mentioned in the Response and specific functions may have already been known. This is not the case here.

The response argues that the references cited by the Examiner do not support lack of patentable utility and the sequence homology with GPCRs is sufficient to justify the functions of the claimed molecules and thus to provide the claimed invention a patentable utility (page 3 of page 3 to 1st paragraph of page 4). This has been fully considered but is not deemed to be persuasive because 35 USC §101 requires disclosure of a specific, substantial, and credible utility. Such a patentable utility has to be a "real world " context of use which does not require significant further research. The instant disclosure asserts that the deduced amino acid sequence encoded by the claimed nucleic acid shares sequence homology with GPCRs without revealing the degree of homology. In view of the diversity of structure and functions of the proteins, prediction of function using comparative sequence analysis may lead to the creation and propagation of assignment errors if not performed appropriately (See,

Peer Bork and Eugene V. Koonin, Predicting functions from protein sequences--where are the bottlenecks? Nature Genetics 18:313-318,1998). There are putative seven transmembrane molecules, which do not appear to be coupled to a G protein (Ji et al. G-protein-coupled receptors, *JBC*, 273:17299-17302, 1998). A change of two-amino acid residues in a protein results in switching the binding of the protein from one receptor to another (Yan et al, Science, 290:523-527, 2000). As the applicants are aware, when the degree of homology is low, there is an even greater risk in predicting the functions of proteins solely based upon the sequence homology.

While sequence analysis is important, the information provided or "predicted" based upon sequence homology can only be used as guidance in determining functions or activities of a molecule by experiments. Any functions predicted based upon the sequence homology will have to be confirmed ultimately by bench work. Such confirmation whether the claimed nucleic acid encodes a functional GPCR requires undue experimentation. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

The Response argues that the instant disclosure provides a patentable utility citing various case laws (2nd paragraph of page4 to page 5). This has been fully considered but is not deemed to be persuasive for the following reasons.

First, the Response cites a device case law. The "device" case law deals with "inopertiveness" under 101 (pertains to perpetual motion machines, for example). The claimed invention in the instant case is drawn to an isolated nucleic acid, not a device

and the instant rejection under 35USC101 is not directed to inoperativeness, but to a lack of patentable utility of the claimed nucleic acid. Thus, applicants' argument citing a case law regarding a device is irrelevant to the instant case.

Second, while the FDA approval is not a prerequisite for finding a compound useful within the meaning of the patent laws and the requirement for the utility of the claimed invention is different from the FDA standard for drug approval, 35 USC §101 does require a specific, substantial, and credible utility, or well-established utility for an invention. The disclosure asserts the utility of the claimed invention in diagnosis and treatment of physiological or behavioral disorders. However, the disclosure fails to provide any evidence and information on the biological functions of the claimed molecules, and fails to identify a disorder or condition that can be diagnosed or treated with the claimed molecules. Without such sufficient information, how can one skilled in the art to use the claimed invention? See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Third, 35 USC §101 requires disclosure of a specific, substantial, and credible utility. Such a patentable utility has to be a "real world " context of use which does not require significant further research. The Response confuses this requirement with the "further research and development" needed in pharmaceutical composition and drug development. In other words, a patentable utility has to be clearly identified or immediately apparent in the disclosure which has nothing to do with the "further research and development" needed in drug development. For example, determining

dosage and administration routes is further research and development, which is acceptable under 35 USC 101 because it is not significant. On the other hand, determining what diseases are to be treated constitutes significant further research and development, which is not acceptable under 35 USC 101.

The Response argues that DNA chips using the claimed nucleotide sequence provide a utility for the claimed invention (last paragraph of page 5 to page 6). This has been fully considered but is not deemed to be persuasive because such utility does not provide a specific and substantial utility for the claimed sequence. Since the disclosure does not reveal any activity/functions of the nucleotide sequence or the protein encoded by the nucleotide sequence, one skilled in the art would not know how to use the claimed sequences.

The Response further argues that the claimed polynucleotide sequence has a specific utility in mapping the protein encoding regions of the corresponding human chromosome (last paragraph of page 6 to top of page 7). This has been fully considered but is not deemed to be persuasive because such a utility is considered a research utility only designed to identify a particular function of the claimed molecules and is not a substantial utility. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility."

The Response argues that persons of skilled in the art, as well as thousand of venture capitalists and investors, readily recognize the utility, both scientific and commercial, of human genomic data (page 7, 2nd paragraph) and that the usefulness of the claimed nucleic acid molecules is substantial and credible and well-established.

This has been fully considered but is not deemed to be persuasive because the disclosure has failed to provide any information or evidence on the biological functions or activities of the protein encoded by the claimed nucleic acid. Without knowing biological functions of the claimed molecules, one of skilled in the art would not know what to do with the claimed invention. Certainly, human genomic data have both scientific and commercial value. However, the commercial value does not simply render the claimed invention a specific, substantial, and credible utility, and the general utility of human genomic information does not simply render the claimed nucleic acid sequences a well-established utility.

The Response argues that the requirement set forth in the Action for compliance with 35 U.S.C. § 101 do not comply with the requirement set forth by the Patent and Trademark Office itself for compliance with 35 U.S.C. § 101. The PTO issued numerous patents on plynucleotide sequences that have not been directly shown to be associated "with any disease or condition" (bottom of page 7). This has been fully considered but is not deemed to be persuasive because each application is examined on its own merit. It should be noted that the examiner has no authority to comment on the validity of the issued U.S. patents.

In summary, the disclosure fails to provide a specific, substantial, and credible utility, or a well-established utility.

IV. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph

The rejection of claims 5-7 under 35 U. S. C. § 112, 1st paragraph remains. The basis for this rejection is set forth at pages 2-6 of the previous Office Action (Paper No. 9, July 30, 2002).

The applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reason set forth above.

V. Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

Ruixiang Li
Examiner
January 13, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER